GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:189
ANSWERED ON:28.11.2007
PRE-IMPORT INSPECTION OF VACCINES
Hasan Chaudhary Munawwar

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether his Ministry has prescribed any pre-import tests for importing various vaccines from abroad;

(b) if so, the details thereof;

(c) whether any violation of this prescription has come to the notice of the Union Government; and

(d) if so, the details thereof and the action taken thereon?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)to(d): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 189 FOR 28TH NOVEMBER, 2007

Quality control of import of vaccines is regulated under the Drugs and Cosmetics Act, 1940, and rules made thereunder. The manufacturing facilities of the vaccine abroad as well as individual vaccines are required to be registered under the said rules prior to their import. The manufacturer is required to provide information in Drug master file containing details of manufacture and testing procedures followed by him as pre requisite to ensure that vaccine from qualified manufacturer is permitted to be imported into the country. Each batch of the imported vaccine is required to be accompanied with the test report and batch release certificate duly signed and authenticated by the manufacturer & National Regulatory Authority of that country. The protocols of test of each batch of the imported vaccine are examined by the National Control Laboratory i.e. Central Drugs Laboratory, Kasauli, before it is released for marketing in the country. However, import of small quantities of vaccines for test and analysis purpose is exempt from system of registration.

No violation of this prescription has come to the notice of the Government.